REMARKS AND RESPONSE TO RESTRICTION REQUIREMENT

Claims 1-30 were pending in the present application. Claims 1-11, 19-23, 26-27, and 30 have been amended. New claims 31-35 have been added. Accordingly, claims 1-35 are currently pending. A marked-up version of the claims titled "Version Showing Changes Made" is attached as Appendix A.

Support for the amendments to the claims and the new claims can be found in the application as filed and/or the claims as previously pending. No new matter has been added.

The Examiner has required restriction of the invention under 35 U.S.C. 121 to one of the following groups:

Group I: claims 1-23, 25 and 27, insofar as drawn to polypeptides encoded by HCV +1 reading frame, nucleic acid encoding the polypeptides, corresponding vaccine composition, and method of use;

Group II: claims 1-4, 10, 14-16, and 25, insofar as drawn to polypeptides encoded by HCV +2 reading frame, vaccine composition, and method of use;

Group III: claims 19-21 and 27, insofar as drawn to nucleic acid encoding polypeptides encoded by HCV +2 reading frame, vaccine composition, and method of use;

Group IV: claims 24 and 26, insofar as drawn to an antibody to a polypeptide encoded by HCV +1 reading frame;

Group V: claims 24 and 26, insofar as drawn to an antibody to a polypeptide encoded by HCV +2 reading frame;

Group VI: claim 28, insofar as drawn to a method of detecting antibodies to an HCV +1 reading frame polypeptide;

Group VII: claim 28, insofar as drawn to a method of detecting antibodies to an HCV +2 reading frame polypeptide;

→ Group VIII: claim 29, insofar as drawn to a method of detecting an HCV +1 polypeptide;

Group IX: claim 29, insofar as drawn to a method of detecting an HCV +2 polypeptide;

Group X: claim 30, insofar as drawn to a method of identifying a compound that binds to an HCV +1 polypeptide;

Group XI: claim 30, insofar as drawn to a method of identifying a compound that binds to an HCV +2 polypeptide.

It is the Examiner's position that the inventions listed as Groups I-XI "do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same of corresponding special technical features."

The restriction requirement issued in the action of September 6, 2002 is improper. Applicants point out that this application is the national stage of PCT/US99/12929 and is being examined pursuant to 35 U.S.C. 371. No objection as to lack of unity of invention was raised during the international phase of the application. Applicants submit that it is improper under the PCT for national offices to require compliance with the requirements relating to the form or contents of the application different from or additional to those which are provided for in the PCT (Art 27 PCT). The PCT Handbook states in section 33.35, paragraph "that a designated office ought not to raise an objection as to a lack of unity when the International Searching and/or Preliminary Examining Authority has found that the claims comply with the requirement for unity of invention." This was agreed to by the Contracting States, according to the PCT Handbook at Section 23.9 paragraph 2, which refers to the report of the PCT assembly, 18th session (1991), item 25.

Applicants have discovered that Hepatitis C virus produces polypeptides in alternate reading frames, e.g., +1 and +2 to the standard open reading frame. The pending claims are all based on this special technical feature. The discovery of alternate reading frame polypeptides is a novel technical feature that links all of these pending claims together. Thus, the claims form a single general inventive concept as required by Rule 13.1.

For the purpose of being responsive, Applicants hereby elect, ***with traverse***, to prosecute the invention of Group VIII, claim 29. In addition to the reasons set forth above, Applicants traverse the restriction requirement to the extent that groups VI, VII, VIII, and IX should be reformed as a single group containing claims 28 and 29 (referred to hereinafter as "newly formed Group VI"). Applicants' grounds for traversal are set forth below.

It is respectfully submitted that Applicants have presented an allowable generic claim, new claim 31, which is generic to the claims set forth in groups VI-IX proposed by the Examiner. New claim 31 is drawn to a method for diagnosing HCV infection comprising detecting the presence or absence of an HCV alternate reading frame polypeptide or detecting the presence or absence of antibodies which bind to an HCV alternate reading frame polypeptide in the body fluid of a subject, wherein the presence of the HCV alternate reading frame polypeptide or antibodies which bind to the HCV alternate reading frame polypeptide is indicative of an infection with HCV.

It is Applicants' position that given the presence of claim 31, which is generic to groups VI-IX proposed by the examiner, a restriction under 35 U.S.C. §121 is improper. In view of the above traversal, Applicants hereby elect ***newly formed Group VI***, claims 28 and 29.

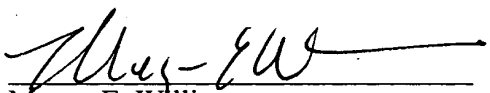
It is Applicants' position that while a species election may be proper for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, an election under 35 U.S.C. §121 is improper since the claims are linked by an allowable generic linking claim. Claim 31 embraces the species of detecting HCV alternate reading frame polypeptides or antibodies that bind to such polypeptides, whether those polypeptides are in the +1 or the +2 reading frame.

If a species election is required, Applicants further provisionally elect Group VIII for search purposes only. It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

CONCLUSION

If a telephone conversation with applicant's agent would expedite the prosecution of the above-identified application, the examiner is urged to call applicant's agent at (617) 227-7400.

Respectfully submitted,



Megan E. Williams
Registration No. 43,270
Attorney for Applicants

LAHIVE & COCKFIELD
28 State Street
Boston, MA 02109
(617) 227-7400

Dated: **September 26, 2002**

VERSION SHOWING CHANGES MADE

1. (Amended) An isolated or recombinant polypeptide [or fragment thereof encoded by a nucleic acid molecule derived from a hepatitis C virus,] comprising an amino acid sequence encoded by a hepatitis C alternate reading frame[having at least one of the following characteristics:

1) at least a portion of the polypeptide is encoded by a reading frame +1 or +2 relative to the standard hepatitis C virus open reading frame;

2) at least a portion of the polypeptide is encoded by a reading frame corresponding to the reading frame of SEQ ID NO:1 in which the first nucleotide of SEQ ID NO:1 is the first nucleotide of a codon;

3) at least a portion of the polypeptide comprises an amino acid sequence at least 60% identical to the amino acid sequence shown in SEQ ID NO:2; and

4) at least a portion of the polypeptide comprises an amino acid sequence encoded by a nucleic acid molecule which hybridizes under high stringency to the nucleotide sequence shown in SEQ ID NO:1].

2. (Amended) The polypeptide [or portion thereof of claim] of any one of claims 1, 32, or 33, wherein [said] the [polypeptide] amino acid sequence is at least about 8 amino acids to at least about 100 amino acids in length.

3. (Amended) The polypeptide [or portion thereof] of claim 2, wherein [said] the [polypeptide] amino acid sequence is at least about 14 amino acids to at least about 30 amino acids in length.

4. (Amended) The polypeptide [or portion thereof] of [claim] any one of claims 1, 32 or 33 wherein [said] the entire polypeptide after the start methionine is encoded by a reading frame +1 or +2 to the standard hepatitis C reading frame.

5. (Amended) The polypeptide [or portion thereof of claim] of any one of clims 1, 32, or 32 wherein [said] the [polypeptide] amino acid sequence is encoded by a reading frame

corresponding to the reading frame of SEQ ID NO:1 in which the first nucleotide of SEQ ID NO:1 is the first nucleotide of a codon.

6. (Amended) The polypeptide [or portion thereof] of claim 5, wherein [said polypeptide or portion thereof] the amino acid sequence is encoded by the nucleic acid molecule of SEQ ID NO:1 and causes an immune response in a subject.

7. (Amended) The polypeptide [or portion thereof] of claim 1, wherein [said] the polypeptide] comprises an amino acid sequence at least about 60% -70% identical to the amino acid sequence shown in SEQ ID NO:2 using FASTA alignment and causes an immune response in a subject.

8. (Amended) The polypeptide [or portion thereof] of claim 1, wherein [said] the polypeptide comprises an amino acid sequence at least 90% identical to the amino acid sequence shown in SEQ ID NO:2 using FASTA alignment and causes an immune response in a subject.

9. (Amended) The polypeptide [or portion thereof] of claim 1, wherein [said] the polypeptide comprises an amino acid sequence shown in SEQ ID NO: 2 [which polypeptide] and causes an immune response in a subject.

10. (Amended) The polypeptide [or portion thereof] of claim 1, wherein [said] the polypeptide comprises an amino acid sequence encoded by a nucleic acid molecule which hybridizes under high stringency to the nucleotide sequence shown in SEQ ID NO:1.

11. (Amended) The polypeptide [or portion thereof] of claim 1, wherein the [which] polypeptide comprises [at least a portion of] an amino acid sequence selected from the group consisting of SEQ ID NO: 3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and SEQ ID NO:8 and causes an immune response in a subject.

19. (Amended) A vaccine composition for preventing hepatitis C infection in a subject comprising a nucleic acid molecule encoding the polypeptide of claim 1.

20. (Amended) A vaccine composition for preventing hepatitis C infection in a subject comprising a nucleic acid molecule encoding the polypeptide of claim 2.

21. (Amended) A vaccine composition for preventing hepatitis C infection in a subject comprising a nucleic acid molecule encoding the polypeptide of claim 4.

22. (Amended) A vaccine composition for preventing hepatitis C infection in a subject comprising a nucleic acid molecule encoding the polypeptide of claim 7.

23. (Amended) A vaccine composition for preventing hepatitis C infection in a subject comprising a nucleic acid molecule encoding the polypeptide of claim 12.

26. (Amended) A kit for detecting a hepatitis C infection comprising an antibody to the polypeptide of any one of claims [claim] 1, 32 or 33.

27. (Amended) A method of preventing HCV infection comprising administering the polypeptide of claim 1 to a subject or by causing [said] the polypeptide to be synthesized is a subject prior to HCV infection such that HCV infection is prevented.

30. (Amended) A method for identifying a compound which interacts with the polypeptide of claim 1, comprising:

contacting said polypeptide with a compound in a cell-free system under conditions which allow interaction of the compound with the polypeptide such that a complex is formed;

separating the compounds which do not form complexes with [an HCV] the polypeptide from those which do form complexes with [an HCV] the polypeptide; and

isolating and identifying the compounds which form complexes with [an HCV] the polypeptide to thereby identify a compound which interacts with the polypeptide of claim 1.